REMARKS

Claims 14-24, as amended, appear in this application for the Examiner's review and consideration. Claim 14 has been amended to recite that the current passes between the electrodes and through the stratum corneum and that the cosmetic composition is applied without the application of mechanical or physical means, support for which is found in the specification, e.g., paragraphs [0067] and [0086] of the published application, as well as in col. 2, ll. 59-67 of U.S. Patent No. 6,148,232, which is incorporated by reference in the present application as stated in paragraphs [0019] and [0057] of the published application. Since no new matter is introduced by this change, the amendment should be entered at this time to reduce issues for appeal and to place the claims in condition for allowance.

Claim Rejections – 35 USC § 112

Claim 14 has been rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action alleges that the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office Action further alleges that the original claims, specification, or drawings do not disclose topically applying a dermatologically effective amount of a composition "without the application of electrical energy".

Applicant respectfully disagrees. The application discloses that first micro-channels are generated by applying electrical energy to the skin and then a cosmetic composition is topically applied to the region in which micro-channels are present (see, for example, paragraphs [0026], [0032], [0051], [0056], [0083], [0085], and [0087] of the published application). According to the present invention, the composition is simply "placed over the region in which micro-channels are present so as to improve the condition of the subject's skin in that region" (see, for example, paragraph [0026] of the published application). In addition, paragraph [0086] of the published application reads:

> According to the invention, the composition is administered topically to a region where micro-channels are present using the apparatus of the invention described herein above. However, the method for treating a skin condition in a subject may optionally further comprise additional steps that can increase the efficiency of topically introducing a composition of the invention into the skin.

> The steps may include mechanical or physical action, or any composition that increases the permeation of the composition of the invention.

Thus, the specification explicitly discloses that the step of topically applying a cosmetic composition according to the present invention does not require the involvement of any mechanical or physical means, such as electrical energy, although the method of the invention may optionally further comprise additional steps, such as mechanical or physical action, that can increase the efficiency of topically introducing a cosmetic composition.

Without acquiescing to the correctness of the rejection and solely for the purpose of advancing the prosecution of the present claims, claim 14 has been amended to replace the phrase "without application of electrical energy" with the phrase "without application of mechanical or physical means that increases the permeation of the composition through the skin" to further clarify that no mechanical or physical means including electrical energy are used when the cosmetic composition is applied to the skin where micro-channels are present. Therefore, the rejection of claim 14 for allegedly failing to comply with the written description requirement has been overcome and should be withdrawn.

Claim 14 has been further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Office Action alleges that "it is not clear how Applicant can claim that the dermatological composition can be topically applied 'without the application of electrical energy' when the application of the composition is taught to occur immediately after an ablation technique which would inherently apply electrical energy to the skin". It is respectfully submitted that the Office Action is not properly considering the recitations of the claims. As indicated hereinabove, while the step of generating micro-channels of course involves application of electrical energy to the skin, but the subsequent step of applying the cosmetic composition to the skin does not (see, for example, paragraphs [0026], [0032], [0051], [0056], [0083], [0085], [0086], and [0087] of the published application). The cosmetic composition is simply applied over the micro-channels without application of any mechanical or physical means that increases the permeation of the composition through the skin and this excludes the application of further electrical energy to the skin as well. Nowhere in the specification is it disclosed that the cosmetic agent is applied immediately after the ablation technique, as alleged in the Office Action. As explained above, the cosmetic composition is

applied over the region in which micro-channels are present, i.e., after micro-channels have been generated. However, it should be noted that as long as the micro-channels remain open, which typically lasts for up to 24 hours, the cosmetic composition can be applied. Thus, after the current is delivered to the skin and the ablation takes place, which is an instantaneous process that lasts one second, the delivery of the cosmetic agent into the skin is achieved without further application of electrical energy, heat energy or other mechanical or physical means affecting the skin that increases the permeation of the composition through the skin. This feature of the presently claimed method further distinguishes from other methods known in the art such as iontophoresis or electrokinetic delivery indicated here in which the agent is delivered into the skin with application of electrical energy. Therefore, the Office Action erroneously concludes on p. 8, last three lines, that "the ablation technique taught by Applicant produces electric heat energy that would inherently affect the uptake of the topical composition by the skin". So the rejection of claim 14 for allegedly failing to comply with the enablement requirement has also been overcome and should be withdrawn.

Claim Rejections – 35 USC § 103

Claims 14-17, 19 and 22-24 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over "Enabling topical immunization via microporation: a novel method for pain-free and needle-free delivery of adenovirus-base vaccines" to Bramson (referred to hereinafter as "Bramson") in view of U.S. Patent Application No. 2002/0161324 to Henley (referred to hereinafter as "Henley '324") in view of U.S. Patent No. 6,302,874 to Zhang (referred to hereinafter as "Zhang").

The Office Action alleges that Bramson teaches a system and method for intradermal delivery of an agent comprising: pre-treating skin by generating a plurality of micro-channels in the skin of the subject by an apparatus comprising: an electrode cartridge (microporation tip comprising ceramic substrate) comprising a plurality of electrodes (80 micron tungsten wires strapped on the substrate are the electrodes) to be oriented generally perpendicular to the skin (even though the tungsten wires are strapped around a ceramic substrate, they still have a perpendicular component to them due to the 80 micron diameter they possess); and a main unit comprising a control unit which is adapted to apply electrical energy between the two or more electrodes in the vicinity of the skin, enabling ablation of the stratum corneum, thereby

generating a plurality of micro-channels having a diameter of about 10-100 microns and a depth of 20-300 microns. The Office Action further asserts that Bramson teaches applying a vaccine via the use of a patch applied to the skin after the channels are created and alleges that Bramson fails to teach a cosmetic composition comprising a cosmetic agent and a carrier devoid of permeation enhancers and further alleges that Bramson fails to teach wherein the electrode cartridge is removably attached to the main unit so that it can be discarded after use.

The Office Action asserts that Henley '324 teaches an electrokinetic delivery device that comprises a main unit that houses the power source and the control circuitry and a separate distal portion that houses the active electrode and a counter electrode and is therefore an electrode cartridge which is detachable from the main unit to enable the main unit to be reusable while the electrode cartridge can be disposed.

The Office Action alleges that Zhang teaches producing transient pores in the skin to facilitate the transdermal delivery of a cosmetic agent composition comprising a cosmetic agent, an acceptable carrier that is devoid of permeation enhancers. The Office Action further alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Bramson to have the copper traces that provide the connection between the electrode cartridge and the main unit be detachable connections like electrical contacts mating with electrical sockets as taught by Henley '324 in order to enable the main unit to be reusable while the electrode cartridge can be disposed. The Office Action further asserts that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device and method of Bramson to apply the patch containing the cosmetic agent and carrier as taught by Zhang to improve the appearance of the skin.

Applicant respectfully disagrees with these allegations stated in the Office Action. Bramson discloses a method of immunization whereby a vaporization process was used to remove tiny areas of the stratum corneum creating microscopic pores that enabled topical immunization using an adenovirus vaccine as a vector for genetic vaccination (see abstract of Bramson). Bramson utilized a device which contained an array of tungsten wires, i.e., resistive elements, which upon passing electrical current became heated and as a result vaporized the cells of the stratum corneum underneath the wires, leaving microscopic holes (micropores; see, e.g., p. 251, right column, and p. 258, right column of Bramson). Thus, the process of microporation as

disclosed by Bramson involves application of thermal energy to the skin by electrically-heated tungsten wires. In contrast, the method for treating a skin condition according to the present invention comprises a step of generating micro-channels by an apparatus that comprises an electrode cartridge comprising a plurality of electrodes and a main unit comprising a control unit which is adapted to apply electrical energy between the electrodes so that the electrical current passes between the electrodes and through the stratum corneum, and only within the cells of the stratum corneum the electrical current is transformed to heat which ablates the cells (see, e.g., paragraph [0067] of the published application and col. 2, lines 59-67 of U.S. Patent 6,148,232, incorporated by reference in the present application). Moreover, claim 14 as amended now recites and claims that the current flow passes between the electrodes through the stratum corneum to enable ablation of the stratum corneum, which is further distinguishable from the disclosure of Bramson.

The Office Action alleges that, since Bramson teaches creating pores and then delivering a composition through the pores, "it would be obvious to one of ordinary skill in the art to use the created pores to deliver any composition, including the cosmetic agents disclosed in the secondary references" (see p. 8, 6th line from bottom of the Office Action). Applicant wishes to emphasize that Bramson teaches a method for delivery of adenovirus-based vaccines. Bramson concludes that the microporation technology has been shown to be effective in enhancing topical application of recombinant adenovirus vectors for gene transfer and genetic immunization (see p. 256, left column of Bramson). However, Bramson acknowledges that while vector administration was accomplished by passive delivery through micropores, delivery of materials requires enhancing technologies (e.g., ultrasound and electroporation; see p. 256, right column of Bramson). Bramson discloses that active delivery processes will not only increase the efficacy of delivery but also reduce the required exposure time (see p. 256, right column of Bramson). Thus, the microporation technique taught by Bramson is not useful as a sole method to deliver materials and active delivery methods are required for that purpose. In contrast, the present invention clearly discloses that efficient transdermal delivery of cosmetic agents was achieved through micro-channels without using any enhancing technologies (see, for example, paragraphs [0014] and [0015] of the published application).

Henley and Zhang do not remedy the deficiencies of Bramson. Henley '324 discloses a method of treatment by electrokinetic self-administration of a medicament into a treatment site

of an individual (see paragraph [0017] of Henley '324). According to Henley '324, a hand-held device electrokinetically drives the medicament into the treatment site (see paragraph [0017] of Henley '324). Thus, Henley '324 does not disclose a method for treating a skin condition whereby a cosmetic composition comprising a cosmetic agent is topically applied to an area of the skin where micro-channels are present and the delivery of the cosmetic agent is by diffusion only, as presently claimed.

Zhang discloses applying a composition containing L-ascorbic acid in conjunction with applying an electrical impulse to the region of the skin (see, for example, col. 3, ll. 61-64 of Zhang). The electric pulse delivers an effective amount of L-ascorbic acid (see, for example, col. 5, ll. 36-38 of Zhang). Thus, even if one of ordinary skill in the art combines the teachings of Bramson, Henley and Zhang, he would obtain a method for transdermal delivery of L-ascorbic acid comprising generating micropores by application of thermal energy to the skin by electrical-heated tungsten wires and applying L-ascorbic acid in conjunction with applying electrical energy so that L-ascorbic acid be delivered electrokinetically. He would not be able to obtain the method for treating a skin condition as recited in claim 14 as follows:

> A method for treating a skin condition in a subject which comprises the steps of:
>
> (i) pretreating skin by generating micro-channels in an area of the skin of a subject by an apparatus which comprises:
>
> (a) an electrode cartridge comprising a plurality of electrodes to be oriented generally perpendicularly to the skin with electrode ends in the vicinity of the skin; and
>
> (b) a main unit comprising a control unit which is adapted to apply electrical energy between two or more electrodes when the electrodes are in vicinity of the skin, typically generating current flow passing between the electrodes and through the stratum corneum, enabling ablation of the stratum corneum in the area beneath the electrodes, thereby generating in the stratum corneum micro-channels having a diameter of about 10 microns to about 100 microns and a depth of about 20 microns to about 300 microns; and
>
> (ii) topically applying to the pre-treated skin and without application of mechanical or physical means that increases the permeation of the composition through the skin a dermatologically effective amount of cosmetic or dermatological composition comprising at least one water-soluble, poorly water soluble or water-insoluble cosmetic agent and a cosmetically or dermatologically acceptable carrier to the area of the skin in which the micro-channels are present so as to improve the skin condition

of the subject, the cosmetic or dermatological composition is devoid of permeation enhancers,

wherein the electrode cartridge is configured and dimensioned for removable attachment to the main unit wherein the cartridge is removably attached to the main unit for applying the electrical energy and thereafter can be detached.

Thus, claim 14 as amended is patentable over Bramson in view of Henley '324 in view of Zhang, and the rejection of this claim under 35 U.S.C. 103(a) should be withdrawn. As claims 15-17, 19, and 22-24 depend from claim 14 and include further recitations thereto, the rejection of these claims should also be withdrawn.

Claims 18, 20, and 21 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Bramson in view of Henley '324 in view of Zhang as applied to claims 14 and 15, and further in view of U.S. Patent No. 6,447,410 to Henley (referred herein after as "Henley '410"). The Office Action asserts that Bramson in view of Henley '324 and Zhang teaches the device and method of claim 15 but fails to teach wherein the cosmetic agent is hydroquinone. The Office Action further asserts that Henley '410 teaches delivery of cosmetic agents to the skin that can include hydroquinone in order to remove pigmentation from hyperpigmented areas of the skin. The Office Action alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device and method of Bramson in view of Henley '324 and Zhang to deliver hydroquinone as taught by Henley '410. The Office Action further alleges that in reference to claims 20, and 21, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device and method of Bramson in view of Henley '324 and Zhang to include an antibacterial agent in the composition as taught by Henley '410 in order to inhibit bacterial growth.

Applicant respectfully disagrees with these allegations stated in the Office Action. As indicated above, Henley '324 and Zhang do not remedy the deficiencies of Bramson. Henley '410 does not remedy the deficiencies of Bramson, Henley '324, and Zhang either. Henley '410 discloses a portable, self-contained, hand-held electrokinetic device for delivering or removing a substance (see col. 1, lines 55-57 of Henley '410). Among the substances to be delivered, antibacterials and hydroquinone are listed (col. 2, line 11 and col. 4, lines 65-66 of Henley '410).

According to Henley '410, the medicament is electrokinetically transported into the treatment site (col. 4, lines 39-41 of Henley '410).

In contrast, the present invention discloses a method for treating a skin condition comprising generating micro-channels and topically applying a cosmetic composition comprising a water-soluble, poorly water-soluble or insoluble cosmetic agent to the area in which the micro-channels are present (see, e.g., paragraphs [0030] to [0033] of the published application). As indicated above, the cosmetic agent according to the present invention is placed over the area where micro-channels are present after removal of the apparatus; no mechanical or physical action including application of electrical energy is used as the cosmetic agent is delivered by diffusion only (see, e.g., paragraph [0026] of the published application). Thus, even if one combines Bramson, Henley '324, Zhang, and Henley '410, he would only obtain a method for delivery of hydroquinone comprising generating micropores by application of thermal energy to the skin by electrically-heated tungsten wires and applying a composition comprising hydroquinone and an antibacterial agent, whereby hydroquinone is electrokinetically delivered. He would not obtain the method as recited in claim 14. As claims 18, 20 and 21 depend directly or indirectly from claim 14 and include further recitations thereto, claims 18, 20 and 21 are patentable over Bramson in view of Henley '324, Zhang and Henley '410 and the rejection of these claims under 35 U.S.C. 103(a) should be withdrawn.

In view of the above, it is respectfully submitted that all current rejections have been overcome and should be withdrawn. Accordingly, the entire application is believed to be in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of this application.

Respectfully submitted,

11/23/10
Date

Allan A. Fanucci (Reg. No. 30,256)

WINSTON & STRAWN LLP
Customer No. 28765
212-294-3311